REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above claim amendments and remarks that follow.

Claim 7 has been amended to incorporate the subject matter o claim 10. Claim 19 has been amended to clarify that the tagging agent is incorporated into the food items. Claims 5, 18, 24, 26, and 27 have been amended to depend on only a single base claim. Claim 10 has been canceled. Claims 1-9 and 11-27 are pending.

Claims 19-20 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,782,762 to Vining *et al*. Applicant respectfully traverses this rejection.

Present claim 19 recites a method comprising administering one or more food items having sufficient tagging agent incorporated therein so that consumption of the one or more food items by the individual causes the stool to become tagged. Applicant respectfully submits Vining *et al*. do not disclose or suggest administering food items having the tagging agent incorporated in the food items themselves.

Vining *et al*. is directed to a method of providing three-dimensional renderings of body organs. At column 8 (lines 1-20), Vining *et al*. briefly discuss methods of preparing the colon for the procedure. These 20 lines are the only disclosure in Vining *et al*. related to methods of preparing the colon for imaging. In one embodiment, Vining *et al*. disclose feeding "a low residue diet combined with a contrast agent (such as a low density barium, for example 1.5% W/V barium)." Thus, Vining *et al*. clearly disclose administering a low residue diet, and a separate contrast agent. Vining *et al*. do not disclose or suggest providing food items with a contrast agent directly incorporated into the food items themselves. Accordingly, Applicant requests reconsideration and withdrawal of the present rejection.

Claims 1-2 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,331,116 to Kaufman *et al*. in view of Cittadini *et al*. (1999, Royal College of Radiologists). Claim 3 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the same combination and further in view of U.S. Patent No. 6,477,401 to Johnson *et al*. Claim 4 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the

combination of Kaufman *et al.* and Cittadini *et al.* and further in view of U.S. Patent No. 5,352,434 to Illig *et al.* Applicant respectfully traverses these rejections.

Applicant respectfully submits the Examiner has failed to provide proper motivation for combining the cited references. Kaufman *et al.* disclose methods for three-dimensional visualization of human organs. At column 16 (lines 37-67), Kaufman *et al.* disclose methods of preparing a colon for visualization. The methods of Kaufman *et al.* avoid the use of laxatives. This is expressly discloses at lines 64-67, and the overall description is in relation to enhancing visualization in the presence of colonic residue. Thus, a skilled person viewing Kaufman *et al.* would understand it to only relates to laxative-free imaging methods.

Cittadini *et al.* describe a study designed to evaluate the ability to obtain satisfactory colon cleansing using oral laxatives (including sennosides) with reduced volume of polyethylene glycol (PEG)-saline solutions. Thus, Cittadini *et al.* only describe methods of colonic cleansing using laxatives. The second paragraph of the Cittadini *et al.* article (page 216, left-hand column) expressly states that thorough cleansing of the large bowel from any fecal content is an absolute requirement. Cittadini *et al.* provide no discussion related to laxative-free alternatives. Thus, a skilled person viewing Cittadini *et al.* would immediately recognize it is only relevant to colonic imaging techniques requiring laxative induced evacuation of the bowels. As pointed out above, Kaufman *et al.* discloses laxative-free methods of imaging the colon. These two methods cannot co-exist. Either the colon is imaged with recognition that residue remains, which is accounted form in the imaging, or the colon is complete evacuated. The Examiner has pointed to nothing indicating components of these two completely opposite imaging methods could be combined. Thus, Applicant respectfully submits the references have been improperly combined.

Even if it is proper to combine references (which Applicant certainly does not suggest), the combination still does not disclose or suggest the invention of claims 1-2. The method of claim 1 incorporates very specific timing of administration of the various components of the colonic tagging components. Specifically, less than 7 doses of a tagging agent are administered over a 20 to 36 hour administration period. Further, 1 to 4 liters of total fluid are administered over the 20 to 36 hour administration period. Finally, the patient is free from administration of laxatives or cathartics for at least 24 hours. The combination of the cited references does not disclose or suggest these specific requirements.

Applicant respectfully points out that each reference must be considered for its full teaching. As pointed out, Cittadini *et al.* mandate colonic cleansing with laxatives. Thus, combining the references would necessarily result in administration of laxatives within 24 hours of the procedure (page 217, left-hand column of Cittadini *et al.* under "Materials and Methods"). Present claim 1 expressly avoids administration of laxatives or cathartics for at least 24 hours.

Applicant further submits the above comments are relevant to the separate rejections of claims 3, 4, and 6. The Examiner wishes to pick and choose elements of Cittadini *et al.* while ignoring the over-arching disclosure that laxatives are mandatory of colonic imaging. This is plainly improper. Rather, a skilled person would not combine these references recognizing they seek mutually exclusive goals: Cittadini *et al.* seek complete colonic cleansing; Kaufman *et al.* and Johnson *et al.* seek imaging despite the presence of colonic residue; the '434 patent to Illig et al. and the '049 patent to Illig et al. merely disclose X-ray contrast compositions. A skilled person would not combine Cittadini *et al.* with the remaining references, particularly Kaufman *et al.* and Johnson *et al.*, in light of its express requirement for complete colonic evacuation.

In light of the above, Applicant respectfully submits claims 1-4 and 6 are not obvious over the combined references. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejections.

Claims 7-9, 11, and 25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Vining *et al.* in view of the Children's Hospital at Westmead (CHW) Fact Sheet. Applicant respectfully traverses this rejection.

Independent claim 7 has been amended to incorporate the subject matter of claim 10. As claim 10 is not rejected over the present combination, Applicant respectfully submits the subject matter of amended claim 7 is not disclosed or suggest by the cited combination. Accordingly, Applicant respectfully submits claims 7-9 and 11 are not obvious over the cited combination, and Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claim 10 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Vining *et al.* in view of the CHW Fact Sheet and further in view of the '049 Illig *et al.* patent. Applicant respectfully traverses this rejection.

As noted above, claim 10 has been canceled. Accordingly, Applicant submits the present rejection has been obviated. As also noted, the subject matter of claim 10 has been incorporated

into independent claim 7. Thus, Applicant submits independent claim 7 (including the subject matter of previous claim 10) is not disclosed or suggested by the present combination.

The Examiner argues Illig *et al.* disclose the use of sorbitol in combination with a contrast agent to reduce the interfacial tension between two immiscible phases (citing column 7, lines 55-59 and column 8, lines 44-56). Applicant respectfully submits the Examiner has mischaracterized the true teaching of Illig *et al.*

At column 7 (lines 55-59), Illig *et al.* do disclose that surfactants or emulsifiers can reduce the interfacial tension between two immiscible phases; however, Illig *et al.* do not disclose that sorbitol is a surfactant or emulsifier. At column 8 (lines 22-24), Illig *et al.* discloses that nonionic emulsifiers or surface active agents can be used. At column 8 (line 32), Illig *et al.* discloses that the nonionic surfactant can be a carboxylic ester. At column 8 (lines 44-48), Illig *et al.* discloses that the carboxylic ester can be the condensation product of fatty and resin partial acids. General examples are provided as fatty or resin acid esters of polyoxyethylene sorbitan and sorbitol. A specific example is polyoxyethylene sorbitan, mono-tall oil esters. Thus, Illig *et al.* do not disclose the use of sorbitol as a surfactant. Rather, Illig *et al.* disclose the use of polyoxyethylene fatty or resin acid esters of sorbitol. These are completely different compounds, and one neither discloses nor suggests the other.

A skilled person would easily recognize that polyoxyethylene fatty or resin acid esters have drastically different structures and functions that sugars, such as sorbitol or mannitol. Accordingly, Applicant respectfully submits Illig *et al.* do not disclose or suggest the use of sorbitol or mannitol with a tagging agent. Applicants, therefore, respectfully submit present claim 7 is neither disclosed nor suggested by the combination of Vining *et al.*, the CHW Fact Sheet, and the '049 Illig *et al.* patent.

Claim 12 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Vining *et al.* in view of the CHW Fact Sheet and further in view of Cittadini *et al.* Applicant respectfully traverses this rejection.

Claim 12 depends upon independent claim 7, which recites administration of a tagging agent in combination with sorbitol or mannitol. Applicant respectfully submits the cited combination does not disclose administration of a tagging agent in combination with sorbitol or mannitol. Moreover, Applicant respectfully points out that Cittadini *et al.* is in no way related to

low residue diets or administration of tagging agents to tag colonic residue. Rather, Cittadini *et al.* is solely directed to studying the effectiveness of laxatives with and without treatment using PEG-saline solutions. Thus, Cittadini *et al.* only discloses methods involving complete colonic evacuation. Thus, there can be no combination of Cittadini *et al.* with references directed to tagging of colonic residue. The unequivocal goal of the methods of Cittadini *et al.* is complete colonic evacuation. Thus, Cittadini *et al.* cannot be viewed as having any connection or correlation to any reference that in any way contemplates incomplete colonic evacuation. Moreover, since Cittadini *et al.* demand total colonic evacuation, it likewise can have not relation to low residue diets. Accordingly, Applicant respectfully submits it is improper to combine Cittadini *et al.* with the remaining references. Applicant therefore respectfully requests reconsideration and withdrawal of the present rejection.

Claims 13-14 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Vining *et al.* Applicant respectfully traverses this rejection.

Present claim 13 recites a method for generating radiography images of an individual's gastrointestinal tract comprising: (i) administering a low residue diet over at least a 48-hour period; (ii) administering one or more doses of a tagging agent over the at least 48-hour period; (iii) imaging the gastrointestinal tract, the patient being free from administration of laxatives or cathartics for at least 24 hours; (iv) producing a radiography image showing stool marked with the tagging agent; and (v) screening the radiography image to identify the presence of any abnormality in the gastrointestinal tract without removing and/or subtracting the marked stool from the images. Applicant submits the method of Vining *et al.* does not disclose or suggest this method.

The Examiner argues Vining *et al.* do not disclose that the step of subtracting retained stool in the images from the final display is a necessary step in their standard method disclosed at column 2 (line 18) through column 3 (line 55). Applicant submits, however, the Examiner has failed to recognize that the method described at column 2 (line 18) through column 3 (line 55) does not contemplate the alternate embodiment disclosed at column 8 (lines 13-20).

Beginning at column 2 (line 35), Vining *et al.* begins the general disclosure of its method for three-dimensional imaging. Lines 35-37 point out that the patient initially undergoes a selected preparation procedure. Line 38 states that, in one embodiment, the preparation

procedure comprises cleansing the colon. Vining *et al.* goes on to describe its imaging method in relation to a patient prepared by colon cleansing (*i.e.*, laxative treatment).

Column 8 (lines 13-20) describe how the standard procedure is changed when a different patient preparation procedure is used. In this embodiment, the preparation procedure involves using a low-residue diet as an alternative to colon cleansing. Thus, in this embodiment, colonic residue remains and this residue is necessarily subtracted from the final display.

The Examiner argues this subtraction step is not necessary in the Vining *et al.* method described at column 2 (line 18) through column 3 (line 55). There is no reason to discuss residue subtraction at this point of the disclosure because the patient has been prepared using laxatives to remove all residue. If colonic residue is present, however, the residue in the image must be subtracted (column 8, lines 13-20). Thus, Vining *et al.* actually discloses two methods. In method 1, the patient is prepped using laxatives to remove all colonic residue, and subtracting is not necessary. In method 2, colonic residue is present, and subtracting of the residue in the image is required. Both methods individually fail to satisfy the requirements of present claim 13.

As noted above, claim 13 requires that the patient be free from laxatives. Method 1 of Vining *et al.* expressly requires laxative treatment to remove colonic residue. Claim 13 also requires that the radiography image is screened without subtracting the marked stool from the images. Method 2 of Vining *et al.* expressly requires subtracting of colonic residue. Applicant respectfully points out that a reference must be considered as a whole, including the portions thereof that teach away from the claimed invention. Vining *et al.* as a whole indicates either laxatives must be used or the colonic residue must be subtracted from the image. Accordingly, Applicant respectfully submits claims 13-14 are not disclosed or suggested by Vining *et al.*, and Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claim 15 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Vining *et al.* in view of Kaufmann *et al.* and Cittadini *et al.* Claim 16 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the same combination and further in view of Johnson *et al.* Applicant respectfully traverses these rejections.

Claims 15 and 16 each depend from claim 13. As noted above, Vining *et al.* do not disclose or suggest the subject matter of claim 13. Moreover, as previously described, Applicant respectfully submits the Examiner has failed to show proper motivation for combining Cittadini

et al. with the remaining references. Cittadini *et al*. only relates to laxative regimens. Yet, the Examiner attempts to combine Cittadini *et al*. with references expressly avoiding laxatives. Such drastically different approaches to patient preparation for colonic imaging cannot be combined. Thus, Applicant respectfully submits claims 15 and 16 are neither disclosed nor suggested by the above-cited combination of references, and Applicant respectfully requests reconsideration and withdrawal of the present rejections.

Claim 17 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Vining *et al*. in view of the '434 Illig *et al*. patent. Applicant respectfully traverses this rejection.

Again, Applicant respectfully submits that Vining *et al*. do not disclose or suggest the subject matter of claim 13, upon which the present claim 17 depends. Moreover, Applicant respectfully submits the Examiner is relying on impermissible hindsight in the alleged disclosure of Illig *et al*. regarding barium dosing.

Illig *et al*. provide a theoretical range of barium concentration in an X-ray contrast composition of 5% to 95% w/w. This covers almost all theoretical concentrations and certainly cannot be relied upon at teaching a specific regimen of three doses of 20 mL each of 40% w/v tagging agent, as presently claimed. The Examiner points to the disclosure at column 9 of Illig *et al*. and alleges the requirements of present claim 17 could be viewed as falling within that disclosure. This is the clearest application of impermissible hindsight.

Illig *et al*. make no disclosure or suggestion of providing a tagging agent in three separate doses. Illig *et al*. make no disclosure or suggestion of providing three separate doses that are each about 20 mL in volume. Illig *et al*. make no disclosure or suggestion of providing three separate doses that each 40% w/v tagging agent. Illig *et al*. provide a broad theoretical range and suggest keeping the dosage "low". What type of dosing regimen may or may not be considered "low" is totally subjective and such evaluation can only be made with hindsight. The term "low" with no further direction does not disclose or suggest a specific regimen of three doses of 20 mL each of 40% w/v tagging agent. To this end, Applicant points out that Illig *et al*. provide 4 examples of its compositions, the largest barium concentration being 19.4% w/v. Thus, since Illig *et al*. teach keeping the dose as low as possible, the real teaching a skilled person would take from Illig *et al*. is that a "low" dose is a single dose of no more than 19.4% w/v.

In light of the above, Applicant respectfully submits claim 17 is not disclosed or suggested by the cited combination. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claims 21-22 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Vining *et al.* in view of Johnson *et al.* Applicant respectfully traverses this rejection.

Claims 21-22 depend from independent claim 19. As pointed out above, Vining *et al.* do not disclose or suggest administering food items with a tagging specifically incorporated into the food items themselves. As the Examiner recognizes, Johnson *et al.* disclose administering barium in a pill form. Thus, the combination of Johnson *et al.* with Vining *et al.* does not overcome the failure of Vining *et al.* to disclose or suggest directly incorporating a tagging agent into food items. Accordingly, Applicant respectfully submits claims 21-22 are neither disclosed nor suggested by the cited combination, and Applicants respectfully request reconsideration and withdrawal of the present rejection.

Claim 23 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Vining *et al.* in view of Cittadini *et al.* Applicant respectfully traverses this rejection.

Claim 23 depends from independent claim 19. Again, Applicant points out that Vining *et al.* do not disclose or suggest administering food items with a tagging specifically incorporated into the food items themselves. Moreover, the portion of Vining *et al.* relied upon by the Examiner specifically requires avoidance of a laxative, relying rather on a low residue diet and subtracting of colonic residue from images. Cittadini *et al.* is fully directed to methods requiring complete evacuation of the colon using a strict laxative regimen. Accordingly, a skilled person would have no motivation to combine Cittadini *et al.* with Vining *et al.*, as suggested by the Examiner. Accordingly, Applicant respectfully submits claim 23 is neither disclosed nor suggested by the cited combination, and Applicants respectfully request reconsideration and withdrawal of the present rejection.

Claims 7-9 stand rejected for nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,866,873. Applicant respectfully traverses this rejection.

The Examiner argues that the method of claim 1 of the '873 patent could require tagging of colonic residue. Applicant respectfully submits that the realm of possibilities does not enter

into an evaluation of obviousness type double patenting. In making an allegation of obviousness type double patenting, the Examiner must point out why the cited claims in the present application would be anticipated by or obvious over the reference claim. Applicant respectfully submits the Examiner has failed to meet this burden.

Nevertheless, Applicant submits the rejected claims in fact are not anticipated by or obvious over the reference claim. Claim 7 expressly recites administering one or more doses of a tagging agent combined with Sorbitol or Mannitol. Claim 1 of the '873 patent makes no mention of administering tagging agents in combination with a dietary regimen. Disclosure of a dietary regimen does not suggest the plethora of different substances that could be also administered. Even if the diet is administered in preparation for a specific procedure, all possible materials that may be administered in relation to the procedure are not suggested as being administered in combination with the diet. For example, the additional material could normally be administered after before cessation of food intake or immediately prior to the procedure. The Examiner must point to some reasoning as to why a skilled person viewing claim 1 of the '873 patent will find it obvious to administer a tagging agent in combination with the diet. The Examiner certainly has pointed to nothing suggesting administering a tagging agent and sorbitol or mannitol, in combination with a specific diet.

In light of the above, Applicant respectfully submits the present double patenting rejection has been improperly applied. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Applicant respectfully submits that all claims, as now submitted, are in condition for immediate allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor formalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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